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CONTRACTING ORGANIZATION:
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**14. ABSTRACT**

This report describes key research accomplishments for Innovative Service Delivery for Secondary Prevention of PTSD between 4/1/09 and 3/31/10. The first annual report and previous quarterly reports detailed the initial, HSRO, Medical University of South Carolina (MUSC), and R&D protocol approval process, the employment and training of study staff, the development of the treatment protocol manual, implementation of study procedures, and the submission of revisions to the protocol. This report focuses on the primary objectives for our second year including: a) recruitment and enrollment, b) the development and implementation of an efficient, sustainable, study-referral infrastructure, and c) presentation of the project at two national conferences and submission and preparation of initial manuscripts. Additionally, we provide a detailed description of the study-related activities that occurred between 01/01/10 and 3/31/10.

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PTSD, OIF/OEF, Telemedicine, Behavioral Activation, Therapeutic Exposure, DOD/VHA research collaborations

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## Introduction

*Purpose and Scope of the Research Project*

The current project has two primary objectives: a) evaluate the effectiveness of an intervention to prevent the functional impairment associated with PTSD and subclinical PTSD in post-deployed OIF/OEF service men and women, and b) determine if this program delivered via telepsychology will be as effective as in-person treatment. Secondary objectives include determining: a) which treatment modality is more effective in terms of process variables (e.g., treatment satisfaction, session attendance), b) which treatment modality is more cost-effective, and c) whether treatment effects differ across race and gender. Behavioral Activation and Therapeutic Exposure (BATE) is an eight-session, manualized treatment program based on two research-supported, therapeutic rationales. Using a non-inferiority design, study participants will be randomized to one of two treatment conditions: BATE delivered via telepsychology (BATE-T), or BATE delivered in-person (BATE-IP). Participants will be assessed across primary and secondary outcome variables at five time points (pre-treatment, mid-treatment, post-treatment, and 3- and 12-month follow up).

Programs that reduce traumatic stress symptoms and related functional impairment will have patient, medical system, and military service-level benefits. At the patient-level, this program may reduce emotional suffering, promote better adjustment to post-deployment life, and lead to better mental and physical health prognosis. At the medical facility-level, this program may reduce service-utilization costs associated with untreated PTSD symptomatology (i.e., by reducing risk for development of physical morbidity and psychiatric co-morbidity associated with untreated PTSD). Furthermore, identification of an innovative service modality (i.e., telemedicine) benefits medical facilities by increasing access to care and reducing costs associated with in-person,

individualized therapy. At the military-service level, this program could reduce attrition and medical leave from military service due to PTSD-related functional impairment.

*Report Overview*

This report presents the primary objectives and accomplishments of our second year (04/01/2009-03/31/2010). We have organized the report into the following sections: Part I: Recruitment and Enrollment, Part II: Clinical Activities, Part III: Research Activities, Part IV: Administrative Activities, Part V: Key Accomplishments, Part VI: Reportable Outcomes, and Part VII: Conclusions and Directions for Year Three. Highlights for the second reporting year include the development of a sustainable referral, recruitment, and enrollment infrastructure, participant completion of Phases I (active treatment) and II (post-treatment), presentation of preliminary findings at national conferences, and submission and preparation of manuscripts.

## PART I: Recruitment and Enrollment

*Current Enrollment*

Project staff prioritized the recruitment, screening, and enrollment of eligible participants. Between 04/01/2009 and 03/31/2010, approximately 185 participants have been screened and 47 have been enrolled bringing our total enrollment to date since the initiation of study procedures on 10/08/2008 to 66. Additionally, 34 participants have completed the eight-session protocol.

*Enrollment Updates by Facility: RHJVAMC, MUSC, and WACH*

*Ralph H. Johnson VAMC.* As described in the first annual report, project staff collaborated with the RHJVAMC PTSD Clinical Team (PCT) to establish a two-tiered assessment system: All OIF/OEF Veterans who endorse PTSD symptoms are referred for evaluation at the PCT clinic by VA health providers. Patients receive a semi-structured psychosocial interview administered by a PCT staff psychologist, followed by a

diagnostic interview (the Clinician Administered PTSD Scale; CAPS) and self-report measures (BDI-II, PCL-M, MINI screener, and demographic questionnaire) administered by members of our research team. Thus, all OIF/OEF Veterans referred for PTSD evaluation at RHJVAMC have the opportunity to meet with our staff, learn about the study, and, if interested, complete the requirements for participation (i.e., consent procedures, eligibility assessment, and randomization).

A significant development involves infrastructure and research office space at the VA Medical Center's major Community-Based Outpatient Clinic (CBOC) in Savannah. Due to its relative proximity to Fort Stewart and Parris Island, this satellite clinic actually serves more OIF/OEF Veterans than our Medical Center. Initial steps have been taken to establish Savannah CBOC as a recruitment site, and we expect to begin enrolling participants from this location within the next 6 months.

*Medical University of South Carolina.* On 03/13/09, the MUSC IRB approved the addition of MUSC as an alternate research site. The addition of MUSC has allowed project staff to recruit and enroll local active duty personnel and Veterans using civilian healthcare services into the study.

Subsequently, project staff has increased efforts to recruit community-residing military personnel into the study. These efforts have included: a) establishing contacts at student Veterans Affairs offices at local colleges and universities (i.e., College of Charleston, Trident Technical College, and Charleston Southern University); b) collaborating with local active duty healthcare providers to encourage referral to the study; and c) consulting with representatives from the MUSC center for translational research to learn unique recruitment ideas.

More specifically, on 10/20/2009, the PI and PC met with Major Monica Lovasz, Director of Psychiatry at the Charleston Air Force Base (AFB) to discuss opportunities for AFB clinic patients to learn about the study. Furthermore, the PC has networked with primary care physicians at the Charleston Naval Base to facilitate the referral of

interested patients to the study. Additionally, on 10/06/09, project staff members met with the Recruitment and Community Engagement Coordinator from the South Carolina Translational Research Institute to learn alternative methods to increase enrollment into the study. Project staff has implemented several of these strategies (e.g., revisions to flyer) to increase community awareness of the project. These efforts have yielded 14 screenings and resulted in the enrollment of five active duty participants and one non-VA Veteran participant living in the Charleston community.

*Winn Army Community Hospital (WACH).* Between 04/01/2009 and 03/31/2010, project staff made significant progress towards securing IRB approval for the addition of WACH as an alternate study site. Please see the previous annual report for a detailed description of compliance activities related to this process during the first year of the study. Below, we provide a timeline of relevant communications, trainings, meetings, and administrative tasks that occurred during the second reporting year.

- **04/07/2009:** The PC contacted the HRPO to request protocol revision status (annual review submitted 03/11/09); formal notification received on 04/08/09.
- **04/13/2009:** The PC contacted the WACH site coordinator (WSC) to request additional documentation per revisions cited in the formal notification.
- **05/08/2009:** The PC received the revised letter of support from the WACH site investigator (WSI); Project staff met with WACH staff at the current site to develop preliminary implementation strategies (e.g., protocol for recruitment, consent procedures, assessment, documentation, and data management) and a safety plan for acutely suicidal patients.
- **05/08/2009:** The PC contacted the DDEAMC IRB. The DDEAMC protocol coordinator requested the following documents: award notice and the USAMRMC protocol approval. The PC was advised that an expedient review process would be likely given that the project fell under the terms of the DoD

intra-institutional agreement, which would may allow the MUSC IRB to serve as the "parent IRB."

- **05/11/2009:** Project staff requested that WACH staff complete required HR paperwork and trainings (i.e., CITI course).
- **05/15/2009:** Project staff e-mailed requested documentation to the DDEAMC IRB.
- **05/28/2009:** Project staff attended strategic planning meeting at WACH to solidify the preliminary procedural manual for study implementation.
- **05/30/2009:** WACH staff submitted HR paperwork and training completion certificates to project staff.
- **05/18/2009, 05/24/2009, 05/26/2009, 06/04/2009, 06/10/2009:** The PC initiated contact with the DDEAMC IRB to inquire about the status of the protocol; contact attempts are unsuccessful.
- **06/10/2009:** The PC contacted the HRPO to request his assistance facilitating contact with DDEAMC IRB. The HRPO provided contact information for the DDEAMC IRB Chair; the HRPO informed the PC that the DDEAMC IRB had recently experienced turnover, which possibly accounted for delays in communication.
- **06/10/2009, 06/12/2009, 06/14/2009:** The PC attempted to contact the DDEAMC IRB Chair by telephone and e-mail; attempts are unsuccessful.
- **06/18/2009:** The DDEAMC IRB Chair contacted the PC and provided the following information: a) The DDEAMC IRB had recently received a large number of protocol submissions, and thus, a potentially lengthy review process should be anticipated, b) the protocol submission package would need to be finalized by the WSI, and 3) the PC would need active duty sponsorship to access IRBNet, the website for protocol submission to DDEAMC IRB; furthermore, sponsorship could not be obtained via DDEAMC IRB staff.

- **06/23/2009:** The PC contacted the HRPO to request sponsorship; the HRPO provided suggestions for sponsors.
- **06/25/2009:** The PC contacted the WSC to request sponsorship; the PC and WSC scheduled a conference call on 06/26/09 to initiate sponsorship procedures (the procedures required that both the sponsor and the spondee complete tasks online within a short time of one another).
- **06/26/2009:** The PC deferred the conference call after experiencing technical difficulties accessing the designated website (the VA server prevented access to the website).
- **06/27/2009:** The PC contacted technical support to facilitate website access.
- **07/20/2009:** The PC received AKO/DKO sponsorship and access to IRBNet; protocol package is created.
- **07/25/2009 through 08/08/2009:** Project staff completed online IRBNet trainings. Information provided in the IRBNet trainings indicated that additional documentation and protocol modifications including securing an onsite medical monitor, other than the WSI, would be required for submission; project staff completed these requirements.
- **10/01/2009:** Project staff uploaded specified documentation to IRBNet and indicated that package was ready for submission pending signatory approval.
- **10/08/2009:** The study package is signed by the WSI and submitted to the DDEAMC IRB. The PC learned that the package would be reviewed on 11/12/2009. Project staff requested to attend the meeting in person per recommendation on the DDEAMC IRB website; alternatively, DDEAMC IRB staff recommended that project staff be available by phone should the reviewers require clarification.
- **11/12/2009:** The DDEAMC IRB reviewed the protocol. Project remained on standby during the meeting in case clarification was required; however, no

phone calls were received during the review meeting. DDEAMC IRB staff notified the PC by telephone later that the protocol was approved pending revisions.

- **12/10/2009:** The PC received official notification of the revisions from the 11/12/2009 committee meeting.
- **01/21/2010:** Based on the notification, project staff scheduled a site visit at WACH to obtain the information required to complete the revisions. Due to conflicting schedules, the meeting is postponed until 02/**08**/2010.
- **02/04/2010:** The WSC notified the PC that she would be deployed to Haiti; the WSC designated two alternate mental health staff members to implement study procedures in her absence.
- **02/08/2010:** Project staff attended meeting at WACH. Information obtained from the meeting is used to complete revisions and prepare the project for resubmission.
- **02/11/2010:** Project staff uploaded the revised package; package was submitted following WSI approval.
- **02/15/2010:** The revised package (second) is reviewed.
- **02/16/2010:** Project staff initiated the required HR paperwork for the additional WACH study staff; New WACH study staff completed required trainings and paperwork.
- **02/17/2010:** Project staff received formal notification of revisions.
- **03/07/2010:** Project staff uploaded the revised package (third); package was submitted following WSI approval.
- **03/15/2010:** The revised package (third) is reviewed.
- **04/16/2010:** DDEAMC notified project staff of revisions and informed staff that the fourth revision package would not require full board review. Further,

the DDEAMC IRB staff informed project staff that pending revisions, approval of the 4th revised package would likely be expedient.

**PART II: Clinical Activities**

*Trainings, Seminars, and Supervision*

On 05/08/2009, Drs. Acierno, Lejuez, and Strachan lead a two-day, BA-TE protocol training for the WACH team and newly hired clinical trainees at the present site. In addition to formal training, trainees at the present site attended weekly clinical seminars led by Drs. Acierno, Strachan, and Tuerk. Seminars covered topics such as exposure-based treatment strategies for PTSD and behavioral activation-based treatment strategies for MDD and associated functional impairment. Additionally, prior to implementing clinical procedures independently, trainees were required to complete the NCPTSD CAPs training course and to shadow our senior-level clinician during a complete, eight-session course of BA-TE.

The PI provided weekly supervision to clinical staff. Additionally, staff attended relevant MUSC and VA clinical seminars.

*Other Clinical Activities*

*Enhancement of the patient agenda planner.* The first annual report described the development of the BA-TE treatment manual and supporting materials. On 07/20/09, consistent with the project mission to create a user-friendly, portable, and accessible protocol for the treatment of PTSD and related functional impairment, project staff consulted with a professional print-shop to enhance the quality of the patient agenda planner.

*Fidelity checks.* Project staff prepared audio recordings of patient sessions for review. An independent rater, trained by the PC in the structural and thematic components of BA-TE, will review session tapes to determine therapist adherence to the protocol.

**PART III: Research Activities**

*Conferences*

*Military Health Research Forum (MHRF), Kansas City, 08/31-09/03/2009.* The PC attended MHRF and presented, "Innovative service delivery for the secondary prevention of PTSD in at-risk OIF/OEF service men and women" at the "Telemedicine" paper and poster sessions. Additionally, the PC attended symposia and plenary sessions related to the study including "PTSD Treatment," the "Impact of War on Soldiers" and "Families and Resilience." The conference provided a unique opportunity to network with telehealth researchers and active duty mental health providers (see *Consultation with Dr. Brian Marx* below).

*Association for Behavior and Cognitive Therapies (ABCT), New York, 11/19-11/22/2009.* Project staff attended ABCT to present preliminary findings during the "Adult Anxiety and PTSD" poster session. Project staff attended relevant symposia including "Behavioral activation as a core process in the treatment of depression: What is it and how to measure it?" and "Innovative ways of investigating how and why patients with PTSD and related disorders change during CBT for PTSD."

*World Congress of Behavior Therapies (WBCT), Boston, 06/02/2010-06/05/2010.* Project staff received notification that "Delivering behavioral activation and therapeutic exposure via telemedicine: Preliminary results" was accepted for poster presentation at the Annual Convention of the World Congress of Behavior Therapies which will be held in Boston in June 2010.

*Abstract submission to ABCT, San Francisco, 11/2010.* Project staff submitted two abstracts, "Predictors of treatment completion in OEF/OIF Veterans with posttraumatic stress disorder" and "Predictors of patient satisfaction in OIF/OEF Veterans receiving behavioral activation/exposure-based treatment for PTSD: Telehealth versus in-person treatment" for poster presentations at the Annual Meeting of the

Association for Behavioral and Cognitive Therapies (ABCT), San Francisco, November 2010.

*Manuscripts*

*Manuscript submission*. Project staff submitted, "Innovative service delivery for secondary prevention of PTSD in at-risk OIF-OEF service men and women" to *Contemporary Clinical Trials*. The article presents the rationale for BA-TE and describes unique aspects of the study design.

*Invited manuscript.* The PI was invited to submit a manuscript to a special issue of Behavior Therapy that will spotlight innovative treatments for anxiety. The manuscript will present preliminary data across primary outcome measures.

*Manuscripts in preparation.* In addition to the invited article, the following manuscripts are currently in preparation: "Predictors of treatment completion in OEF/OIF Veterans with posttraumatic stress disorder;" "Predictors of patient satisfaction in OIF/OEF veterans receiving behavioral activation/exposure-based treatment for PTSD: Telehealth vs. in-person treatment; " "Behavioral activation and therapeutic exposure for PTSD: Treatment manual;" "DoD and VHA research collaborations: Lessons learned;" and "Behavioral activation treatments for PTSD: A review."

**PART IV: Administrative Activities**

The following section summarizes key protocol modifications, IRB amendments, personnel additions, consultation with co-investigators and collaborators, and inventory management.

*Key Protocol Modifications: MUSC, PTSD Diagnosis, PC-Based Telemed technology (similar to "Skype")*

***1. Addition of MUSC as an alternate research site:*** As summarized above, project staff amended the protocol to include MUSC as an alternate research site. The addition of MUSC allows for the recruitment of local active duty personnel and Veterans

who use civilian healthcare into the study. The amendment was submitted on 02/25/09 and approved on 03/13/09.

***2. Inclusion of participants with PTSD:*** Staff provided justification to Parameshwar Mahasreshti for inclusion of participants with PTSD on 02/17/09. The amendment was approved by the MUSC IRB on 03/13/09 and by the study sponsor on 07/09. Detailed justification for the amendment is included in the first annual report that was submitted 04/30/09.

***3. Inclusion of Skype Technology:*** Several Veterans expressed an interest in home-based telemedicine using computers instead of videophones. This was investigated as a viable alternative, and it was discovered that the Veterans Administration has an approved vendor supplying FIPS level encryption (Federal Government Standard) for use on personal and VA computers. Administrative application for permission to use this form of PC based video communication was made and received.

***Other Amendments*** (***Approved by the MUSC IRB):***

- **Amendment #10, Approved 04/03/09:** Change in payment schedule - $20 added for completing the post-assessment
- **Amendment #11, Approved 07/23/09:** Change in personnel
- **Amendment #12, Approved 09/02/09:** Change in advertisement - updated contact number
- **Amendment #13, Approved 09/21/09:** Change in personnel
- **Amendment #14, Approved 11/02/09:** Change in personnel
- **Amendment #15, Approved 12/21/09:** Change in advertisement - changed contact number as well as other suggestions by MUSC's SUCCESS Center
- **Amendment #16, Approved 01/14/10:** Change in personnel
- **Amendment #17, Approved 04/08/10:** Change in personnel

*Audits*

Per institutional standard, the VA Research Compliance Officer audited the study on 09/28/2009; we passed with accolades.

*Personnel*

To meet the growing demands of the project, we hired two research assistants and a masters-level therapist. Research assistants managed data and inventory and tracked patients throughout the duration of the study. Additionally, staff developed tools to facilitate study procedures including: a) the creation of a PDF desktop library comprised of relevant journal articles, b) the creation of a patient tracking system to alert clinicians about upcoming appointments, follow-up assessments, etc., and c) development of an updated study "discharge" packet which included a description of and contact information for non-profit agencies serving Veterans in the Charleston tri-county area.

*Weekly Lab Meetings*

Project staff attended weekly lab meetings to discuss administrative issues including protocol adherence, data management, patient tracking, randomization procedures, and compliance.

*Consultation with Dr. Brian Marx*

A primary objective of the current study is to determine whether BA-TE can alter the course of PTSD-related functional impairment. Dr. Brian Marx of the National Center for PTSD is currently conducting a four-year clinical trial to develop and evaluate a self-report inventory to assess PTSD-related functional impairment in OIF/OEF service men and women. The Index of Functional Impairment (IFI) self-report questionnaire assesses functional impairment across psychosocial domains. Currently in Phase II of development, Dr. Marx has generously permitted us to include a preliminary version of the IFI in the baseline, post, 3-month and one year follow-up assessments; the addition of the IFI will enhance our ability to measure change in functional impairment as a function of symptom reduction.

*Financial Report for Year Two*

**PART V: Summary of Key Accomplishments**

- **05/08/2009:** Dr. Carl Lejuez conducts behavioral activation training for WACH staff.
- **05/28/2009:** Staff visits Winn Army Community Hospital to develop preliminary procedural manual.
- **07/01/2009:** Project staff interview and hire an additional protocol therapist.
- **08/31/2009-09/03/2009:** PC presents "Innovative Service Delivery for the Secondary Prevention of PTSD in at risk OIF/OEF Service Men and Women" at MHRF.
- **11/19/2009-11/22/2009:** Project staff, attended ABCT to present preliminary study data during the "Adult Anxiety and PTSD" poster session.

- **01/2010-02/08/2010:** In collaboration with the WSC, the PC drafts preliminary procedural manual for WACH.

- **02/2010:** The PI was invited to submit a manuscript to a special issue of *Behavior Therapy* that will spotlight innovative treatments for anxiety.

- **02/08/2010:** Project staff attend onsite meeting at WACH

- **03/2010:** Abstract accepted for poster presentation at the Annual Convention of the World Congress of Behavior Therapies (Boston, June, 2010).

- **03/02/2010:** Project staff submitted two abstracts for poster presentations at ABCT, (San Francisco, November, 2010).

- **03/31/2010:** Project staff submitted manuscript detailing treatment and study design to *Contemporary Clinical Trials*.

**PART VI: Reportable Outcomes**

*Participant Characteristics*. Baseline data for 57 participants (52 male, 5 female) living in the southeastern United States are presented below. Fifty -percent of participants reported they were married while 23% reported they were divorced or separated (25% reported they were never married). Notably, 34% of the sample reported they were unemployed. The majority of the sample was Caucasian (54%), followed by African-American (41%) and Other (4%).

Tables 1 and 2 provide the mean and range for primary baseline assessment measures and PTSD diagnostic status.

*Table 1: Baseline assessment measures: Diagnostic status, mean score, and range*

| **Measure** | **Mean score** | **Range** |
|---|---|---|
| BDI-II | 22.67 | 3-54 |
| PCL-M | 55.73 | 26-83 |
| BAI | 24.0 | 1-55 |
| DAST | 19.36 | 16 -20 |
| AUDIT | 16 | 9-34 |

*Table 2: PTSD diagnostic status per CAPs*

| | |
|---|---|
| PTSD | 33 |
| Subthreshold PTSD | 23 |

## PART VII: Conclusions and Future Directions

*DoD VA Research Collaborations*

Project staff has worked diligently to create an infrastructure to facilitate future DOD/VA research collaborations. Procedural changes implemented by project staff during the second reporting year were consistent with the project mission: develop and evaluate a brief, telehealth-based, user-friendly treatment protocol that targets both traumatic stress symptoms and related functional impairment. During our third year, project staff will continue to focus on recruitment and enrollment, providing weekly clinical supervision, and presenting findings at national conferences.

## References

There are no references for the current report.

## Appendices

No appendices are included in the current report.